Taltz

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
II/0053	Extension of indication for TALTZ to include treatment alone or in combination with methotrexate, of active JPsA and ERA in patients 6 years of age and older and with a body weight of at least 25 kg, who have had an inadequate response to, or who are intolerant of, conventional therapy, based on week 16 results from study I1F-MC-RHCG.	24/07/2025	22/08/2025	SmPC and PL	Please refer to Scientific Discussion: Taltz EMEA/H/C/003943/II/0053

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

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	As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 8.2 of the RMP has also been updated. Furthermore, the PI is in line with the latest QRD template version 10.4. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				
II/0054	Update section 4.8 of the SmPC to add eczematous eruptions (dyshidrotic eczema and exfoliative dermatitis) to the list of adverse drug reactions (ADRs) with frequency uncommon and rare, respectively, following a review of all associated data. The package leaflet is updated in accordance. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	12/06/2025	22/08/2025	SmPC and PL	Not applicable SmPC new text For more information, please refer to the Summary of Product Characteristics.
X/0051	Extension application to add a new strength of 40 mg for Taltz, Solution for injection Annex I_2.(c) Change or addition of a new strength/potency	30/01/2025	28/03/2025	SmPC, Labelling and PL	
PSUSA/10493 /202403	Periodic Safety Update EU Single assessment - ixekizumab	31/10/2024	n/a		PRAC Recommendation - maintenance

IA/0050	A.7 - Administrative change - Deletion of manufacturing sites	28/05/2024	n/a		
II/0049/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.I.a.1.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Replacement or addition of a site where batch control/testing takes place and any of the test method at the site is a biol/immunol method	20/04/2023	n/a		
II/0048	B.I.a.2.c - Changes in the manufacturing process of the AS - The change refers to a [-] substance in the manufacture of a biological/immunological substance which may have a significant impact on the medicinal product and is not related to a protocol	09/02/2023	n/a		
II/0046	Update of section 4.8 of the SmPC in order to add 'oesophageal candidiasis' to the list of adverse drug reactions (ADRs) with frequency rare based on a safety review of all associated data; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and update instructions for use to clarify information on product stability at room temperature. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	12/01/2023	05/01/2024	SmPC and PL	For more information, please refer to the Summary of Product Characteristics.

IG/1565	A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	06/12/2022	n/a		
II/0045/G	This was an application for a group of variations. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.II.a.3.b.5 - Changes in the composition (excipients) of the finished product - Other excipients - Change that is supported by a bioequivalence study B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size B.II.e.1.a.3 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Sterile medicinal products and biological/immunological medicinal products	16/12/2021	28/11/2022	SmPC, Labelling and PL	As a result of this group of variations, sections 4.8 and 6.1 of the SmPC are being updated to reflect that the introduction of a citrate free formulation to improve tolerability. Section 4.8 of the SmPC is updated as follows: The results described above are obtained with the original formulation of Taltz. In a single-blinded, randomized cross-over study in 45 healthy subjects comparing the original formulation with the revised, citrate-free formulation, statistically significantly lower VAS pain scores were obtained with the citrate-free vs. the original formulation during injection (difference in LS Mean VAS score -21.69) and 10 min after injection (difference in LS Mean VAS score -4.47). Section 6.1 of the SmPC is updated as follows: Sucrose Polysorbate 80 Water for injections Sodium hydroxide may be used to adjust pH The labelling and Package Leaflet (PL) are updated

					accordingly (concerning ingredients). For more information, please refer to the Summary of Product Characteristics.
PSUSA/10493 /202103	Periodic Safety Update EU Single assessment - ixekizumab	28/10/2021	n/a		PRAC Recommendation - maintenance
T/0044	Transfer of Marketing Authorisation	29/07/2021	12/08/2021	SmPC, Labelling and PL	
II/0040	Update of section 5.1 of the SmPC with long-term efficacy and safety data in axial spondyloarthritis from study RHBY - A multicenter, long-term extension study of 104 weeks, including a double-blind, placebo-controlled 40-week randomized withdrawal–retreatment period, to evaluate the maintenance of treatment effect of ixekizumab in patients with axial spondyloarthritis. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	17/06/2021	12/08/2021	SmPC	Patients who completed one of the three Axial Spondyloarthritis pivotal studies COAST V/W/X (52 weeks) were offered participation in a long term extension and randomised withdrawal study (COAST Y, with 350 and 423 patients enrolled on Taltz Q4W and Q2W, respectively). Among those who achieved remission 157/773 (20.3%) (Ankylosing Spondylitis Disease Activity Score [ASDAS] <1.3 at least once, and no ASDAS score ≥2.1, at weeks 16 and 20), 155 patients exposed to Taltz up to 76 weeks were randomised at week 24 of the COAST Y study (Placebo, N=53; Taltz Q4W, N=48; and Taltz Q2W, N=54); of these, 148 (95.5%) completed the week 64 visit (Placebo, N=50; Taltz Q4W, N=47; Taltz Q2W, N=51). The primary endpoint was the proportion of patients in the randomised withdrawal population who did not experience a flare during weeks 24 64 (combined Taltz Q2W and Taltz Q4W groups versus placebo). A significantly larger proportion of patients (NRI) in the combined Taltz groups (83.3% (85/102), p<0.001) and Taltz Q4W (83.3 % (40/48), p=0.003) had no flare during weeks 24 64 compared with those who withdrew from Taltz to placebo (54.7 % (29/53)). Taltz (in both combined Taltz groups and

					Taltz Q4W group) significantly delayed the time to flare (Log Rank Test p<0.001 and p<0.01, respectively) compared to Placebo. In patients who received Taltz Q4W continuously (N=157), the ASAS40, ASDAS<2.1 and BASDAI50 responses were maintained to Week 116. In conclusion, data from the randomized placebo-controlled withdrawal-retreatment study shows that, in patients who achieved sustained remission, continuous treatment with ixekizumab reduces the likelihood of experiencing a flare.
II/0041	B.I.b.1.f - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Change outside the approved specifications limits range for the AS	11/03/2021	n/a		
IB/0042	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	05/03/2021	n/a		
II/0038/G	This was an application for a group of variations. Clinical studies in adult plaque psoriasis: Type II- C.I.4 -Update of section 5.1 of the SmPC regarding long term data in the treatment of psoriasis: RHAZ, RHBA, RHBC (3 studies of the "UNCOVER" series) were the pivotal registration studies, with response data up to 60 weeks already included in the SmPC. The current update relates to the extension data available, covering a total of 5 years. Section 5.1 of the SmPC has also been updated with	14/01/2021	12/08/2021	SmPC	The long-term efficacy data from the studies submitted in plaque psoriasis and psoriatic arthritis supports a long term sustained efficacy in this adult population treated with Taltz. The risk profile from these additional studies is also consistent with the known safety profile for Taltz (described in the currently approved SmPC), and there were no new clinically important safety findings with this long-term data submission.

	information from study RHCR (known as "IXORA-R") which is a 24-week head-to-head comparison of Taltz vs guselkumab. Clinical studies in adult psoriatic arthritis: Type II- C.I.4 -Update of section 5.1 of the SmPC regarding long term data in the treatment of psoriatic arthritis: RHAP and RHBE (also known as SPIRIT-P1 and P2) were pivotal registration studies, with response data at 24 weeks and up to 52 weeks (SPIRIT-P1) already included in the SmPC. The current update relates to extension data available covering a total of 3 years. Section 5.1 of the SmPC has also been updated with longer-term data from study RHCF ("SPIRIT-H2H" Taltz vs adalimumab). Response data of up to 24 weeks are already in the SmPC and the addition of 52 week data are being made. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
R/0039	Renewal of the marketing authorisation.	15/10/2020	17/12/2020	SmPC, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Taltz in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.

PSUSA/10493 /202003	Periodic Safety Update EU Single assessment - ixekizumab	29/10/2020	n/a		PRAC Recommendation - maintenance
II/0034	B.I.a.1.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Replacement or addition of a site where batch control/testing takes place and any of the test method at the site is a biol/immunol method	02/07/2020	n/a		
II/0031	Extension of Indication to include the treatment of moderate to severe plaque psoriasis in children from the age of 6 years and with a body weight of at least 25 kg and adolescents who are candidates for systemic therapy; as a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2, 6.4 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. The PI was also brought in line with the latest QRD template version 10.1. The RMP version 7.2 has also been agreed. The variation leads to amendments to the Summary of Product Characteristics, Annex II, and Package Leaflet and to the Risk Management Plan (RMP). C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	28/05/2020	26/06/2020	SmPC, Annex II, Labelling and PL	Please refer to Scientific Discussion 'Taltz-H-C-003943-II-31'
IB/0035	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	24/06/2020	17/12/2020	SmPC and PL	
IAIN/0037/G	This was an application for a group of variations.	22/06/2020	n/a		

	A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient A.7 - Administrative change - Deletion of manufacturing sites B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing				
II/0030	Extension of indication to include treatment of adult patients with active axial spondyloarthritis; as a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC and relevant section of the PL are updated. The PI was also brought in line with the latest QRD template version 10.1. Furthermore, the applicant took the opportunity to update the local representative of Estonia in the PL. In addition, the RMP was updated to version 6.3. The variation leads to amendments to the Summary of Product Characteristics, Annex II and Package Leaflet and to the Risk Management Plan (RMP). C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	30/04/2020	02/06/2020	SmPC and PL	Please refer to Scientific Discussion 'Taltz-H-C-3943-II-0030'
IB/0033	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process	30/04/2020	n/a		

	of the AS				
N/0032	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	17/03/2020	02/06/2020	PL	
PSUSA/10493 /201903	Periodic Safety Update EU Single assessment - ixekizumab	03/10/2019	n/a		PRAC Recommendation - maintenance
IB/0029/G	This was an application for a group of variations. B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place	08/08/2019	n/a		
II/0026/G	This was an application for a group of variations. Type II- C.I.4 -Update of section 5.1 of the SmPC based on results of study RHCF - a 52-Week Multicenter, Randomized, Open-Label, Parallel-Group Study Evaluating the Efficacy and Safety of Ixekizumab versus Adalimumab in Patients with Psoriatic Arthritis Who Are Biologic Disease-Modifying Anti-Rheumatic Drug Naïve. Type II- C.I.4 -Update of section 4.5 of the SmPC based on results of study RHBU – a study evaluating of the effect of ixekizumab on the pharmacokinetics of cytochrome P450 substrates in patients with	18/07/2019	02/06/2020	SmPC	The Product information has been updated with results from a drug-drug interaction study in patients with moderate-to-severe psoriasis, which determined that 12 weeks of administration of ixekizumab with drugs metabolized by CYP3A4 (i.e., midazolam), CYP2C9 (i.e., warfarin), CYP2C19 (i.e., omeprazole), CYP1A2 (i.e., caffeine) or CYP2D6 (i.e., dextromethorphan) does not have a clinically significant impact on the pharmacokinetics of these drugs. In addition, results from a study investigating the efficacy and safety of Taltz in a multicenter, randomized, open-label, rater-blinded, parallel-group study (SPIRIT-H2H) compared to adalimumab (ADA) in 566 patients with PsA

	moderate-to-severe plaque psoriasis. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				who were naïve to biologic disease-modifying anti-rheumatic drugs (bDMARD) were also reflected in the product information. Taltz was superior to ADA on the primary study objective: simultaneous achievement of ACR 50 and PASI 100 response at Week 24 (Taltz 36.0% vs ADA 27.9%; p=0.036; 95% confidence interval [0.5%, 15.8%]). Taltz also showed non-inferiority (pre-specified margin of -12%) to ADA on ACR 50 ((ITT analysis: 3.9% difference vs. ADA; 95% confidence interval [-4.3%; 12.1% ; PPS analysis Taltz: 52.3%, ADA: 53.1%, difference: -0.8% [CI: -10.3%; 8.7%]) and superiority on PASI 100 at Week 24 (60.1 % with Taltz vs 46.6% with ADA, p=0.001), which were the major secondary endpoints in the study.
IA/0027	B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method	23/05/2019	n/a		
PSUSA/10493 /201809	Periodic Safety Update EU Single assessment - ixekizumab	11/04/2019	n/a		PRAC Recommendation - maintenance
II/0025/G	This was an application for a group of variations. B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP -	14/02/2019	n/a		

	Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method				
PSUSA/10493 /201803	Periodic Safety Update EU Single assessment - ixekizumab	04/10/2018	n/a		PRAC Recommendation - maintenance
IB/0021	B.I.e.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	29/08/2018	n/a		
IB/0022	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	20/08/2018	n/a		
N/0023	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	30/07/2018	06/02/2019	PL	
II/0018	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	25/05/2018	06/02/2019	SmPC and PL	
II/0014	B.I.e.2 - Introduction of a post approval change management protocol related to the AS	26/04/2018	n/a		
II/0016	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	19/04/2018	06/02/2019	SmPC and PL	
PSUSA/10493 /201709	Periodic Safety Update EU Single assessment - ixekizumab	12/04/2018	n/a		PRAC Recommendation - maintenance

IAIN/0017	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	15/02/2018	n/a		
IG/0898	A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient	12/02/2018	06/02/2019	Annex II	
II/0009	Extension of Indication to include Ixekizumab alone or in combination with methotrexate, the treatment of active psoriatic arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drug (DMARD) therapies. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, and 5.2 of the SmPC are updated to reflect the new safety and efficacy information. The Package Leaflet and RMP have been updated accordingly. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	14/12/2017	18/01/2018	SmPC and PL	Please refer to the published Assessment Report Taltz H-3943-II-09-AR.
PSUSA/10493 /201703	Periodic Safety Update EU Single assessment - ixekizumab	12/10/2017	08/12/2017	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10493/201703.
IB/0012/G	This was an application for a group of variations.	10/10/2017	n/a		

	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure				
IA/0011	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	31/08/2017	n/a		
IB/0008	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	26/04/2017	n/a		
PSUSA/10493 /201609	Periodic Safety Update EU Single assessment - ixekizumab	06/04/2017	n/a		PRAC Recommendation - maintenance
IA/0007	B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place	07/02/2017	n/a		

IB/0006	B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate	14/12/2016	n/a		
IAIN/0004	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	15/11/2016	n/a		
N/0002	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	14/10/2016	07/09/2017	Labelling and PL	
IB/0003	B.II.f.1.d - Stability of FP - Change in storage conditions of the finished product or the diluted/reconstituted product	12/10/2016	07/09/2017	SmPC and PL	
IA/0001/G	This was an application for a group of variations. A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	02/06/2016	n/a		